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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,483	09/15/2003	Robin Fong	GC775-2	2423

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,483	Applicant(s) FONG ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-13, 15-19, 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 5, 14, 20-22 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The amendment to the specification filed May 26, 2006 has not been entered because it is in improper format. The amended paragraph does not contain amendment markings as is required by 37 CFR 1.121(b)(1)(ii). It should also be noted that in the listing of the claims, the claim number for claim 4 was omitted.

The amended drawings filed May 26, 2006 have not been entered because they are in improper format. The amended drawings are not labeled "Replacement Sheet" as required by 37 CFR 1.121(d). Further, if non-color drawings are to be used in the application, then references to colors in the drawings (see, e.g., paragraph [13] of the specification) also need to be amended.

2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

3. The abstract of the disclosure is objected to because it is insufficiently detailed. The abstract should recite that a preferred protein of interest is an immunoglobulin or fragment thereof, and should recite that the chromatography involves the use of hydrophobic charge induction chromatography. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 9, line 14, of the specification. Applicant is required

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to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The pH ranges recited in claims 14 and 15 are not recited in the specification. The number of steps range recited in claim 17 is not recited in the specification. The method of claim 25, in which an immunoglobulin is not required to be purified from its fusion analog, is not recited in the specification.

6. Instant claims 1-4, 6-13, 16, 18, and 19 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Instant claims 5, 14, 15, 17, and 20-30 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a protein which is a peptide concatamer or which is a fragment of an enzyme, a fragment of a peptide concatamer, a fragment of a hormone, a fragment of a growth factor, a fragment of a receptor, or a fragment of a vaccine; does not disclose the pH gradient ranges recited in claims 14 and 15, and does not disclose that the pH gradient can range from low to high or from high to low; does not disclose a step pH gradient comprising between two and six steps; does not disclose HCIC binding and elution done in a batch process; does not disclose HCIC resin in a packed column, in an axial flow column, in a radial flow column, or in an expanded bed column;

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and does not disclose purifying an immunoglobulin wherein the immunoglobulin is not required to be purified from its fusion analog.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 5, 14, 20-22, and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Power et al (U.S. Patent Application Publication 2004/0018573). Power et al teach separating free IgG1 from glucoamylase-IgG1 fusion proteins by hydrophobic charge induction chromatography. In the purification method, the fermentation broth is clarified, its pH is adjusted to 8.2, it is applied to the HCIC column, the column is washed, and the free IgG1 is eluted by incrementally decreasing the pH in four steps, ultimately down to 2.5. See paragraph [0160].

The disclosure of Power et al relied upon in the above rejection is not disclosed in Power et al's provisional application 60/373,889. Accordingly, Power et al is not available as prior art under 35 U.S.C. 102 against any of the instant claims which are entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/411,537.

9. Applicant's arguments filed May 26, 2006 have been fully considered but they are not persuasive.

The objection to the drawings set forth in section 2 of the first Office action and the objection to the disclosure set forth in section 4 of the first Office action are maintained because the amendments to the drawings and to the specification were not entered for the reason set forth in section 1 above.

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Applicants did not respond to the objection to the Abstract set forth in section 3 of the first Office action and repeated above.

The objection to the specification set forth in section 6 of the first Office action and repeated above is maintained. This objection merely requires that the specification be amended to recite verbatim language found only in the claims. That original claims are considered part of the original disclosure, and that original claims may be “self-supporting” is irrelevant to this objection. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

The examiner maintains his position with respect to the effective filing date of Applicants’ claims and the claim for priority under 35 U.S.C. 119(e). Applicants did not contest the examiner’s analysis with respect to instant claims 5 and 25. Applicants cite to pages 13 and 15 of provisional application 60/411,537 as support for the pH range of instant claims 14 and 15. However, the disclosure in the provisional application of a pH of 8.2 is not support for the wider pH range of “about 8”, and the disclosure of a beginning pH of 8.2 is not support for a final pH of about 8. Applicants cite to the provisional application’s disclosure of a four step pH gradient as support for instant claim 17. However, the disclosure of a four step pH gradient does not support the broader range recited in the claim.

Applicants argue that the anticipation rejection based upon Power et al (U.S. Patent Application Publication 2004/0018573) should be withdrawn because Applicants’ provisional application was filed before the filing date and publication date of Power et al. However, as indicated in section 6 above, the rejected claims are not entitled under 35 U.S.C. 119(e) to the benefit of the filing date of Applicants’ provisional application. Accordingly, for these claims, it is not relevant that Applicants’ provisional application was filed before the filling date and

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publication date of Power et al. Power et al remains prior art against instant claims 5, 14, 20-22, and 25-28 under 35 U.S.C. 102(e).

The rejection under 35 U.S.C. 103(a) based in part upon Power et al (U.S. Patent Application Publication 2004/0018573), set forth in section 10 of the first Office action, is withdrawn in view of Applicants' statement of common ownership at page 9, second full paragraph, of Applicants' response.

The rejection of claim 25 over the Guerrier et al article (Bioseparation, Vol. 9, pages 211-221) set forth in section 11 of the first Office action is withdrawn in view of the amendment to the claim requiring a pH gradient which is incrementally decreased.

10. Claims 1-4, 6-13, 15-19, 23, and 24 are allowed. Claim 3 is would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

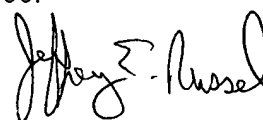
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and a cursive "E".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 5, 2006